REMARKS

Applicants have amended the claims to more particularly define the invention in view of the outstanding Official Action. Claims 2 and 11 have been amended as fully supported by the specification as originally filed. Claim 2 has been amended to specify that the injection of said pasty medicine into the holding portion results in expansion of the filling member after the filing member has been implanted in the spinal segment or the intervertebral space, whereby the filling member is securely lodged in the spinal segment or the intervertebral space upon completion of the solidification of the pasty medicine as supported by original claim 2, lines 2 and 3. Claim 11 has been amended to specify that wherein the layers of the laminated multi-layer wall are laminated in such a way that the pores of the layers are not necessarily aligned, and that the laminated multi-layer wall is permeable to liquid and the laminated multi-layer wall do not allow passage by solid as supported by the specification page 5, lines 10-13 and page 8, lines 3-7. Thus, these amendments are fully supported by the specification as originally filed as would be appreciated by one of ordinary skill in the art to which the invention pertains.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 U.S.C. 112 and clearly patentable over the references of record.

The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Reiley in view of Coutts and further in view of Kuslich has been carefully considered but is most respectfully traversed in view of the amendment to the claim.

The rejection of claims 2, 10 and 12-16 under 35 U.S.C. 103(a) as being unpatentable over Reiley in view of Coutts has also been carefully considered but is most respectfully traversed in view of the following comments.

The methodology of Applicants' presently claimed invention and Reiley's and Coutt's are different methodologies in which the presently claimed invention comprises

an Inserting Step and Treating Step, both of which are different and unobvious from the cited references as would be appreciated by one of ordinary skill in the art to which the invention pertains. Reiley's invention comprises the Inserting Step, Cavity Forming Step and Treating Step, whereas Coutt's invention comprises only the Cavity Forming Step and Treating Step.

Although the presently claimed invention and Reiley's invention both comprise the Inserting Step, both consist of different functions, ways and results. For example, Applicants' function is to put in the implant in order to conduct a Treating Step whereas Reiley's function is to put in a tool in order to conduct Cavity Forming Step. Applicants way is to put in the air-permeable implant into vertebra - the implant would remain in the human body. Reiley's way, on the other hand, is to put the non-air permeable tool into the vertebra - in order to complete Cavity Forming Step, the tool has to be non air-permeable and the tool has to be removed in the last step of the Cavity Forming Step. The result of Applicants' presently claimed invention, as illustrated in the attached photo, is that the implant that makes bone cement remain in the implant and forms a complete clump that has enough strength whereas the result of Reiley's invention is, after the tool is removed, the cavity would make bone cement form into stick shape, but the strength is still not powerful and adequate.

The traditional method, which does not use the Cavity Forming Step, is to inject bone cement directly into cancellous bone, thus it is unable for bone cement to form a single complete clump that contains not enough strength. Sometimes accidents would occur when bone cement leaks out of the vertebra and which would be unable to have the collapsed vertebra to reinstate its normal sharp. Reiley's method was to use the Cavity Forming Step to pre-form a cavity, thus the injected bone cement could form a stick shape clump, but the strength is weak. In addition, Reiley's method uses introduction of filling material into an expandable body to compact the cancellous bone in order to form a cavity, thus it is able to have the collapsed vertebra to reinstate its normal sharp.

The method of Coutt's was to also use the Cavity Forming Step, thus the injected bone cement could form a stick shape clump, but the strength was weak. In addition, Coutt's method uses ream to remove cancellous bone in order to form a cavity, thus would never be able to have the collapsed vertebra to reinstate its normal sharp.

Applicants method does not include the Cavity Forming Step, however, it has been discovered by Applicants that there is no need to pre-form a cavity in order to have bone cement form a real single complete clump. A modified Treating Step could do the same and to have the collapsed vertebra reinstate its normal step. Applicants can therefore conclude that the strength in their present invention is higher than the strength in both Reiley's and Coutt's inventions as would be appreciated by one of ordinary skill in the art to which the invention pertains.

The Treating Step is comprised in Applicants' presently claimed invention, as well as Reiley's and Coutt's, however, Applicants functions, ways and results differ from both Reiley's and Coutt's. The functions of Applicants present invention is that the bone cement forms a high strength single clump and the collapsed vertebra reinstates its normal shape. In this regard, both Reiley's and Coutts' function is that the bone cement forms a clump that has a certain degree of strength. Applicants note that both their and Reiley's inventions are similar in that one function includes the collapsed vertebra to reinstate its normal strength, however, clearly it is the <u>strength</u> of the clump in each invention that differs which results from the presently claimed invention.

The way of Reiley's and Coutt's present invention is to inject bone cement into pre-formed cavity. In addition, in Reiley's invention, to prevent bone cement leak out from vertebra, injection has to be conducted when the viscosity of bone cement is higher. However, Applicants ways are to inject bone cement into air-permeable implant (vessel) of pore size having a diameter less than 0.1mm. Bone cement is kept in the vessel, thus could be injected while the viscosity is low and the stick shape clump is not formed. The result of both Reiley's and Coutt's invention forms stick shape clumps, however, Applicants result forms a single complete clump. In addition, the clump has

enough strength in Applicant's present invention whereas the strength in both Reiley's and Coutt's invention is insufficient.

The Examiner states that Reiley's invention discloses in figures 40-41 and column 24, line 15-47 states that "a single layer permeable filling member 510 receiving a pasty material while placed within the spine". The Examiner further states that "Reiley further discloses a connection tube to expel the cement within the mesh". As a matter of fact, the vessel of Applicants present invention and the mesh 510 of Reiley's invention is not identical, they are neither identical in "expel the cement within the mesh".

The functions, ways and results of Applicants present invention and Reiley's invention differ as such. The functions of Applicants present invention are to inject bone cement into the vessel and form a single complete clump with sufficient strength, prevent bone cement to leak out from vertebra and inject bone cement into the vessel and have collapsed vertebrae reinstate its normal shape. Reiley's functions are to inject bone cement into the vessel and form a clump that has a certain degree of strength wherein strength is weaker and prevent bone cement to leak out from vertebra. In addition, the effect of Reiley's invention is made by the tool in Cavity Forming Step, not by mesh in Treating Step. Applicants ways are to put an implant into vertebra during Inserting Step, vessel and nozzle combine and form a filling member, inject bone cement into air-permeable implant of pore size have a diameter less then 0.1 mm. Bone cement is kept into the vessel, thus injection could be made while the viscosity of the cement is low, the clump that vessel has deploys is the total cubic area, and vessel needs to have bone cement (viscous material) to be non-permeable substantially, thus pore size have a diameter less then 0.1 mm.

However, Reiley's ways are, during the Treating Step (as shown in Fig. 41) the viscous flow of filling material 96 injected from the tip 90 carries the mesh 510 into the cavity 84 in advance of the filling material 96, the physician drapes the mesh 510 over the tip 90, as FIG. 40 shows, tip 90 and mesh 510 do not integrate, which is not filling

member, the viscous flow of filling material 96 injected from the tip 90 carries the mesh 510 into the cavity 84 in advance of the filling material 96, inject bone cement on mesh 510, to inject part of cavity, not all --- The mesh presents a surface area, which is about 1/3rd to 1/2 of the interior area of the main therapeutic cavity 84 formed by the selected expandable body.(column 24, line 33-36),and the mesh 510, permeated with viscous material 96.(column 24, line 45-46), thus pore size of mesh 510 is bigger.

The results of Applicants present invention are to form single complete clump, the clump has sufficient strength and the collapsed vertebrae could reinstate its normal shape whereas Reiley's results are to form a shape clump, the clump has insufficient strength and the collapsed vertebra could reinstate its normal shape.

The Examiner has stated that "Reiley fails to disclose the size of the pores in the mesh filling member 510. It would have been an obvious matter of design choice to Describe modification and press to make the holes to have a diameter less then 0.1 mm, since such a modification would have involved a mere change in the size of a component." However, it could be concluded obviously from the above statement that Applicants' presently claimed invention is not "a simple mere change in the size of a component", and which is based on different doctrine, needs and function that the methodology involved long time research and development (see A). The effect of Applicants present invention is superior to the reference cases (see A, B). Moreover, if Applicants present invention uses the mesh 510 of Reiley's invention, it will never reach the purpose of Applicants present invention.

The attached photo indicates the Applicants simulated experiment on the vertebra module, which was followed by Applicants present invention (left side of the photo) and the methodology of Reiley. The result has shown that Applicants present invention could form a single complete clump according to vessel shape and methodology of Reiley's invention could form a stick shape of clump. It could be concluded that besides that the methodology and cited reference are different for Applicants present invention, Applicants' presently claimed invention has a surprising improvement as would be appreciated by one of ordinary skill in the art to which the

invention pertains. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In addition to the above comments, please consider the attachment which is a summary comparison of the presently claimed invention and the cited prior art.

In view of the above comments and further amendments to the claims favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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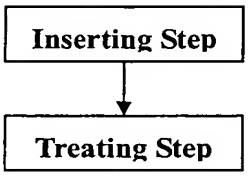
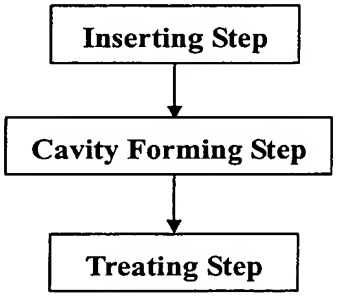
(A) The methodology of the Invention and the reference case of US-6248110(referred to as case "110"), US-5514137(referred to as case "137") are different methodology, which could be elaborated as follows:

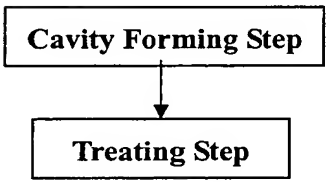
The methodology of the invention:



Case "110"



Case "137"



Further analysis is listed as follows:

	1. Inserting Step	2. Cavity Forming Step	3. Treating Step
Case "137"	No	Yes	Yes
Case "110"	Yes	Yes	Yes
The invention	Yes(but different from the Inserting Step of Case "110")	No	Yes(but different from the Treating Step of Case "110" and Case "137")

The differences among the invention, Case"137" and Case "110" in terms of comparing Inserting Step, Cavity Forming Step and Treating Step are as follows:

1. Inserting Step : Both the invention and the Case "110" contain Inserting Step, but both consist of different function, way and result, the analysis is as follows:

	The Invention	Case "110"	Difference
Function	To put in the implant in order to conduct treating Step	To put in tool in order to conduct Cavity Forming Step	Different
Way	To put in the air- permeable implant into vertebra---The implant would remain in human body.	To put the non air permeable tool into the vertebra---in order to complete Cavity Forming Step, the tool has to be non air-permeable and the tool has to be removed in the last step of the Cavity Forming Step.	Different
Result	The implant that makes bone cement remain in the implant and forms a complete clump that has enough strength. (see the attached photos)	After the tool is removed, the cavity would make bone cement form into stick shape, but the strength is still not powerful. (see the attached photos)	Different

2. Cavity Forming Step :

(a)Traditional Method : not include cavity forming step. To inject bone cement directly into cancellous bone, thus it is unable for bone cement to form a single complete clump that contains not enough strength. Sometimes accident would incur when bone cement leaks

out the vertebra and which would be unable to have the collapsed vertebra to reinstate its normal sharp.

(b) Case "137" : use cavity forming step to pre-form a cavity, thus the injected bone cement could form a stick shape clump, but the strength is weak. In addition, the case uses ream to remove cancellous bone in order to form a cavity, thus would never to be able to have the collapsed vertebra to reinstate its normal sharp.

(c) Case "110" : use cavity forming step to pre-form a cavity, thus the injected bone cement could form a stick shape clump, but the strength is weak. In addition the case uses introduction of filling material into an expandable body to compact the cancellous bone in order to form a cavity, thus it is able to have the collapsed vertebra to reinstate its normal sharp.

(d) The Invention : not include cavity forming step, but it was accidentally found that there's no need to pre-form a cavity in order to have bone cement form a real single complete clump. A modified treating step could do the same and to have the collapsed vertebra reinstate its normal sharp. And we conclude that the strength is higher than the Case "110" and "137"

3. Treating step : The Invention and Case"137" and Case "110" contain Treating Step, but having different function, way and result, the analysis is as follows:

	The Invention	Case"110"	Case "137"	Difference
Function	1. bone cement to form a high strength single clump. 2. the collapsed vertebra to reinstate its normal sharp.	1. bone cement to form a clump that has certain degree of strength 2. the collapsed vertebra to reinstate its normal sharp	1. bone cement to form a clump that has certain degree of strength	Identical in some degree
Way	To inject bone cement into air-permeable implant(vessel) of pore size have a diameter less then 0.1 mm.	To inject bone cement into pre-formed cavity To prevent bone cement leak out from vertebra, injection has	To inject bone cement into pre-formed cavity.	Different

	Bone cement is kept in the vessel, thus could be injected while the viscosity is low and the stick shape clump is not formed.	to be conduct when the viscosity of bone cement is higher.		
Result	1.Form single complete clump 2.The clump has enough strength 3. the collapsed vertebra could reinstate its normal shape	1.Form stick shape clump 2.The clump has insufficient strength 3. the collapsed vertebra could reinstate its normal shape	1. Form a stick shape clump 2. Strength of the clump is insufficient.	Different

(B) The Examiner states that in Case "110" that "Reiley discloses in figures 40-41 and column 24,line 15-47states that "a single layer permeable filling member 510 receiving a pasty material while placed within the spine". The Examiner further states that "Reiley further discloses a connection tube to expel the cement within the mesh". As a matter of fact, the Vessel of the Invention and the mesh 510 of Case "110" is not identical, they are neither identical in "expel the cement within the mesh". Comparisons of function, way and result are as follows:

	The Invention	Case "110"	Difference
Function	1. Inject bone cement into vessel and form a single complete clump with sufficient strength. 2. Prevent bone cement to leak out from vertebra. 3. Inject bone cement into vessel and have collapsed vertebra reinstate its normal shape.	1. Inject bone cement into vessel and form a clump that has certain degree of strength (strength is weaker) 2. Prevent bone cement to leak out from vertebra. 3. No. The effect of Case "110" is made by the tool in cavity forming step, not by mesh in treating step.	Not completely identical
Way	1. To put implant into vertebra during inserting step.	1. During treating step, as FIG. 41 shows, the viscous flow of filling material 96 injected from the tip 90 carries the mesh 510 into the	

		cavity 84 in advance of the filling material 96.	
	2. Vessel and nozzle combine and form a filling member.	2.the physician drapes the mesh 510 over the tip 90, as FIG. 40 shows, tip 90 and mesh 510 do not integrate, which is not filling member ,	
	3. To inject bone cement into air-permeable implant of pore size have a diameter less then 0.1 mm. Bone cement is kept into the vessel, thus injection could be made while the viscosity of the cement is low.	3. the viscous flow of filling material 96 injected from the tip 90 carries the mesh 510 into the cavity 84 in advance of the filling material 96.	
	4. The clump that vessel has deploys is the total cubic area.	4.inject bone cement on mesh 510, to inject part of cavity, not all --- The mesh presents a surface area, which is about 1/3rd to 1/2 of the interior area of the main therapeutic cavity 84 formed by the selected expandable body.(column 24, line 33-36)	
	5. vessel needs to have bone cement (viscous material) to be non-permeable substantially, thus pore size have a diameter less then 0.1 mm	5.The mesh 510, permeated with viscous material 96.(column 24, line 45-46), thus pore size of mesh 510 is bigger	
Result	1. To form single complete clump. 2. The clump has sufficient strength. 3. The collapsed vertebra could reinstate its normal shape	1. To form stick shape clump. 2. The clump has insufficient strength. 3. The collapsed vertebra could reinstate its normal shape	

(C) The Examiner has stated that "Reiley fails to disclose the size of the pores in the mesh filling member 510. It would have been an obvious matter of design choice to Describe modification and press to make the holes to have a diameter less then 0.1 mm, since such a modification

would have involved a mere change in the size of a component.". However we could conclude obviously from the above statement that the This invention is not "a simple mere change in the size of a component", and which is based on different doctrine, needs and function that the methodology involved long time research and development(see A). The effect of the Invention is superior to the reference cases (see A, B). Moreover, if the Invention uses the mesh 510 of Case "110", it will never reach the purpose of the Invention.

(D) The attached photo indicates the inventor's simulated experiment on the vertebra module, which was followed by the invention (left side of the photo) and the methodology of Case "110". The result has shown that: the Invention could form a single complete clump according to vessel shape and methodology of Case "110" could form a stick shape of clump. We could conclude that besides the methodology and reference case are different for the Invention, it also concludes that the Invention has a surprising improvement.